TARC TOWNHALL MEETING

MONDAY, MAY 6TH
4:00-5:30PM
Agenda Overview

- Welcome Remarks
- TARC Updates
  - Budget
  - Strategic Plan
  - Pilot Grants
- Introducing New Faculty
- TARC Stakeholder Advisory Board Updates
- T32 Funding Announcement
- UNC CCCR Updates
  - Methodology Core
  - Resource Core
- The OAAA Updates
- Clinical Trials Updates
- DEI Workgroup
- TARC Research Seminar Series Updates
- TARC Research Day 2024
- TARC Chalk Talks
- Walk to Cure Arthritis 2024
- Q&A w/TARC Leadership
- Social
Budget Updates
TARC Operational Budget >$500k / year

- IT / HR / Finance (pre- and post-award), $270,000
- University Exp. (Misc.), $25,000
- TARC Event / Meetings, $12,000
- Communication/Phone, $12,000
- Admin. Supplies / Storage, $24,000
- Staff, $180,000
- Repair/Service, $11,000
- University Exp. (Misc.), $25,000
### TARC Indirect F&A (15.6% of total F&A)

FY23 compared to FY24

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<th>July</th>
<th>August</th>
<th>September</th>
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<tr>
<td>2023</td>
<td>50k</td>
<td>100k</td>
<td>150k</td>
<td>200k</td>
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<td>2024</td>
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F&A cumulative is $35.8k greater in Apr 2024 than Apr 2023.

**Difference between TARC operating budget and F&A ~ $175k**
Strategic Plan Updates
Basic, Translational and Clinical Research
Clinical Trials
Education
Clinical Care
Marketing and Communications
Strategic Goal: Advance, Expand and Further Integrate our Basic, Translational and Clinical Research

Working groups leads: Kelli Allen (clinical), Doug Phanstiel and Onyi Iweala (Basic and Translational)

Objective 1: Expand TARC research through recruiting additional investigators including those working in new content areas

1.1 Action: Recruitment

- Recruit a clinical investigator with expertise in an area that complements current TARC research
  **Astia Allenzara, MD**
- Recruit additional physician scientist(s) in Rheumatology with research expertise in immunology (innate immunity or adaptive immunity)
- Co-recruit a PhD immunologist (with Microbiology and Immunology or Genetics) to complement research in immunology, autoimmunity, and/or the immunology of allergy.

1.2 Action: Interdepartmental collaboration to expand research in several key areas:

- Expand TARC research in Health Outcomes, Health Disparities, and Quality Improvement
- Increase interaction with departments and centers on campus that have research expertise in areas that would complement TARC research
  Examples: Orthopedics, new School of Data Science
Advance, Expand and Further Integrate our Basic, Translational and Clinical Research

Objective 2: Improve TARC infrastructure for scientific collaboration

2.1 Action: Create a position for a TARC “senior or lead project coordinator” to help to centralize processes, support early career investigators & maximize TARC research support.

2.2 Action: Develop and maintain a centralized data base of human samples and clinical data held by TARC investigators and promote its use in collaborative studies.

https://www.med.unc.edu/tarc/research/clinical-databases-and-biorepositories

2.3 Action: Develop a TARC Scientific External Advisory Board

Visit of Dr. Joel Block MD, Chief, Division of Rheumatology, Rush Medical College
Sept 16-18
Advance, Expand and Further Integrate our Basic, Translational and Clinical Research

Objective 3: Improve TARC infrastructure for scientific collaboration

3.1 Action: Continue applications for shared equipment through the SOM that could be utilized by multiple TARC investigators.

3.2 Action: Improve opportunities for social interaction among investigators (e.g., happy hours, lunches, etc.)

TARC Town Hall

3.3 Action: Hold mini retreats with invited speakers from other departments/centers to promote new collaborations.
Advance, Expand and Further Integrate our Basic, Translational and Clinical Research

Objective 4: Build Community & efficiency among TARC research personnel

4.1 Action: Develop structures & opportunities for research staff to share experiences & resources

   Groups formed: 1) Research study coordinators and 2) Lab Managers

4.2 Action: Provide opportunities for relationship-building among research personnel

4.3 Action: Explore potential for a more centralized group of research staff who could contribute to different projects depending on time & funds

Objective 5: Enhance diversity of TARC faculty and staff

5.1 Action: Make diversity a priority for recruitment including trainees who may be future faculty

5.2 Action: Increase interaction with diversity programs on campus including PREP, SPIRE, WinSPIRE, Carolina Postdoctoral Fellows for Faculty Diversity, etc. and make sure our research program is known as an outstanding place for these trainees.

5.3 Action: Increase interaction with local universities (particularly those that serve URM) including identifying and inviting potential TARC research seminar speakers.
TARC/CCCR Pilot Grants
# TARC/CCCR Pilot Grants

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<tr>
<th>Principal Investigator(s)</th>
<th>Co-Investigator(s)</th>
<th>Project Title</th>
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<tbody>
<tr>
<td>Jason Franz</td>
<td>Brian Pietrosimone; Lara Longobardi; David Berkoff</td>
<td>Pain-mediated effects of quadriceps muscle dysfunction on inflammation and cartilage loading in individuals with OA</td>
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<tr>
<td>Yvonne Golightly</td>
<td>Amanda Nelson; Steve Marron</td>
<td>Machine Learning Approaches to Inform Biomechanical Subtypes of Knee Osteoarthritis</td>
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<tr>
<td>Brian Pietrosimone; David Lalush</td>
<td>Caroline Lisee; Jason Franz; Jeff Spang</td>
<td>Limb Underloading post-ACL Reconstruction and Increased Cartilage Strain: Identifying Biomechanical Phenotypes at Risk for Posttraumatic Osteoarthritis and the Potential for Precision Gait Retraining in Posttraumatic Osteoarthritis Prevention</td>
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New TARC Faculty
Ming-Feng Hsueh, PhD
Assistant Professor
Orthopaedic Surgery

Research Interests
- Osteoarthritis
- Cartilage regeneration
- Proteomics analysis of musculoskeletal tissue
- Non-coding RNAs in articular joints
TARC Stakeholder Advisory Board
Objectives

• Established in Spring of 2018 with small pilot Stakeholder Engagement grant from the UNC CTSA
• TARC physicians recommended patients with representative disease diagnoses including osteoarthritis, rheumatoid arthritis, and systemic lupus erythematosus, and allergies.
• TARC SAB members were diverse in terms of gender, race and ethnicity. The initial SAB had 8 members. Several more have been added over time.
• A member of the SAB was designated as Chair.
TARC
Stakeholder Advisory Board

• A Stakeholder member brings their unique experiences, knowledge, views and ideas to the research study.

• He or she provides feedback and opinions throughout the TARC research process, beginning with the start of the research idea to putting the results into practice.
Stakeholder Advisory Board Book
Objectives

• Discuss what research is, and why we do it
• Discuss other related activities conducted at TARC
• Explain how these activities fit within the Thurston Arthritis Research Center (TARC) structure and mission
• Introduce the Core Centers for Clinical Research (CCCR)
• Define the “players” in research
• Describe the role of Stakeholder/Patient Representatives in research
TARC SAB Meetings and Engagement

- TARC SAB met monthly in person from March 2018 – March 2020 on the second Friday of each month.
- Beginning in April 2020, the SAB began meeting by zoom calls monthly.
- TARC SAB attends the yearly TARC Research Day Conference which is held in October in person (except for 2020 and 2021).
- Researchers communicate with the SAB through the Chair by email if input is required between meetings.
Selected Projects with TARC SAB Involvement

- Guidance for OAAA patient education materials
- UNC Core Center for Clinical Research (CCCR) renewal application
- Input to the UNC Institute for Health Sports and Performance
- Recruitment storyboard for The OA Prevention Study (TOPS)
- Input on ways to recruit participants for a penicillin allergy evaluation and de-labeling
- Input on a study of telehealth delivery of a weight loss intervention in older adults with multiple chronic conditions
T32 Funding Announcement
T32 Funding Announcement

Drs. Leigh Callahan and Amanda Nelson Receive T32 Award for Training Program at UNC

The Rheumatic and Musculoskeletal Disease Epidemiology and Outcomes Training Program at the University of North Carolina

The overall goal of this T32 is to provide state-of-the-art resources and a rich environment to train independent researchers who will improve our understanding of the magnitude, etiology, impact, and treatment of rheumatic and musculoskeletal diseases (RMDs), and who will assume leadership roles in RMD epidemiology and outcomes research.

Their interdisciplinary program includes trainees and faculty across UNC, including TARC, Epidemiology, Biostatistics, Statistics and Operations Research, Medicine, Nursing, Physical Therapy, and Exercise and Sports Science.
The overall goal of the University of North Carolina (UNC) Core Center for Clinical Research (CCCR) is to provide state-of-the-art resources and a rich environment to optimize clinical studies in rheumatic and musculoskeletal diseases (RMDs) with a focus on osteoarthritis (OA), to advance clinical care and public health efforts targeted toward individuals with RMDs.
**Methodology Core**

Provide support for advanced and innovative statistical methodologies to the research community

Deliver educational materials and training for clinical RMD studies

Advisory, Brainstorming, and Consultative (ABC) sessions

Speaker series
**Resource Core**

Provide advice and analytic services for phenotyping and precision medicine

Encourage broader implementation of these approaches

ABC sessions

Speaker series
Renewal Resource Core

**Aim 1a: Illumination Health dataset development**
- Admin Core
- Method Core
- IAB
- SAB
- EAB
- UNC

**Aim 1b: Deidentified UNC CCCR OA dataset**

**Aim 2: Consultation**
- BIOS
- TARC
- STOR
- BWH
- UNC

**Aim 3: Training**
- SDSS
- PPMH
- NC TraCS
- CHIP

### Y1 Aim 1a
- UNC: develop computable phenotype, gold standard case reviews
- Illumination Health (IH): initial dataset characterization

### Y2 Aim 1a
- UNC: adjust phenotype, troubleshoot PheCAP implementation
- IH: Run PheCAP with input from Harvard P30 (Liao)

### Y3 Aim 1a/b
- UNC: troubleshoot initial dataset and receive revised final version
- IH: Finalize dataset, completely de-identify, send to UNC

### Y4 Aim 1b
- UNC: begin work with final dataset, initial analyses and begin advanced phenotyping, disseminate to initial interested collaborators
- IH: address any missing features, data types, other issues that arise

### Y5 Aim 1b
- UNC: house cleaned dataset and complete first analyses, begin initial precision medicine analyses, and disseminate to Research Community more broadly
Mission:
The Osteoarthritis Action Alliance’s mission is to improve lives by elevating OA as a health priority and leading the dissemination of innovative evidence-based solutions

- Increase **awareness** about the prevalence and seriousness of OA
- Expand **education** for healthcare providers, people who have OA, policymakers, community organization leaders
- Focus on **solutions** for both the prevention and management of OA through delivery of tools, resources, and evidence-based programs

https://oaaction.unc.edu/
Clinical Trials at TARC
May 6th, 2024

Shruti Saxena Beem
Lead Clinical Research Coordinator
TARC Clinical Trials Team
Sheikh Research Team
TARC Clinical Trials Team Vision Statement

Our vision is to ensure equitable opportunities for patients to access cutting edge therapeutics and innovative programs to enhance their health and well-being, and to integrate clinical trials into the day-to-day care of our patients.
Lupus Studies: Actively Recruiting

Cell Therapy  Non-Cell Therapy  Biorepository

- Lupus Nexus Landmark Study: A Prospective Registry and Biorepository
- Clinical data linked biospecimens and molecular data
First controlled trial testing the efficacy of this therapy compared to standard of care in SLE

MiSLE: A Phase 2 sequential dose-escalation study evaluating the safety and feasibility of allogeneic umbilical cord derived mesenchymal stromal cells for the treatment of adults with treatment refractory lupus
Cell Therapy Lupus Studies

- **BMS CAR-T**: A Phase 1, multicenter, open-label study of CD19-targeted NEX-T chimeric antigen receptor (CAR) T cells, in severe, refractory SLE

- **Cabaletta CAR-T**: A Phase 1/2, Open-Label Study to Evaluate the Safety and Efficacy of Autologous CD19-specific Chimeric Antigen Receptor T cells in Active SLE
UNC Lupus Cellular Therapy Clinical Trials Working Group Coordinators

Shruti Saxena Beem  
Rheumatology

Roger Huamani Velasquez  
Rheumatology

Catherine Cheng  
Hematology/Cell Therapy

Kelly Hoye  
Hematology/Cell Therapy
Non-Cell Therapy Lupus Studies

**ALE10 (DIVERT):** A Phase 2, Double-Blind, Placebo-Controlled Trial of Mycophenolate Mofetil alone or with Voclosporin for Systemic Lupus
- Explore and compare pre-randomization gene expression patterns among responders and non-responders to MMF and MMF plus voclosporin

**AMETHYST:** Evaluate the efficacy and safety of BIIB059 compared to placebo in participants with active Cutaneous Lupus or SLE
- **BIIB059** is an mAb that works upstream of other type 1 IFN–interfering drugs. BIIB059 binds the BDCA-2 receptor on pDCs, leading to inhibition of type 1 IFN production
Osteoarthritis Studies

TOPS
- The Osteoarthritis Prevention Study (TOPS)
- Phase 3 trial to determine efficacy of lifestyle strategies (weight loss, nutrition, or exercise) in preventing the development of knee OA

Vitamin K
- 6-month pilot study to determine if supplementing with Phylloquinone (vitamin K1) can help knee osteoarthritis vs placebo
  - Age ≥ 50 years
  - Patient reports chronic knee discomfort
Transportation/Expenses
- Study team sets up round trip Lyft/Uber rides for research visits

Hotel/Lodging

Meals for Study Visits

Decentralized Trials

Childcare Reimbursement

Spanish Language Resources
- Opt-in or request patient-facing study materials in Spanish for all new studies
- Bilingual (English/Spanish) staff to support Hispanic participants

Research Participant Support Initiatives
DEI Workgroup
Meet our DEI Workgroup Members

#Whatadiversityofficerlookslike
## TARC Research Seminar Series (noon-1pm): Upcoming Events

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<tr>
<th>Date</th>
<th>Speaker</th>
<th>Affiliation</th>
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<tr>
<td>Friday, May 17th</td>
<td>Onyinye Iweala, MD, PhD</td>
<td>UNC, Division of Rheumatology, Allergy, and Immunology</td>
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<tr>
<td>Friday, September 6th</td>
<td>Duncan Lascelles</td>
<td>NC State University, College of Veterinary Medicine</td>
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<tr>
<td>Friday, November 8th</td>
<td>Erin Steinbach</td>
<td>UNC, Division of Rheumatology, Allergy, and Immunology</td>
</tr>
<tr>
<td>Friday, December 13th</td>
<td>Matthew Fisher</td>
<td>Joint Department of Biomedical Engineering, UNC and NC State University</td>
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TARC Research Day 2024

This Year’s Co-Chairs: Lara Longobardi and Amanda Nelson

We Look Forward to Seeing You at TARC Research Day 2024!

October 25th, 2022; 8:00 a.m. to 2:30 p.m.; UNC Friday Center, Chapel Hill, N.C.
We’re excited to announce our Keynote Speaker and John B. Winfield, MD Visiting Scholar for this year’s TARC Research Day meeting. See details below.

More information and updates regarding this event will be announced in the coming months.

Keynote Speaker & John B. Winfield, MD Visiting Scholar

Virginia B. Kraus, MD, PhD
Distinguished Professor of Medicine
Professor of Pathology
Professor in Orthopaedic Surgery
Duke University School of Medicine

Department of Medicine
Duke University School of Medicine
TARC Chalk Talks
**TARC Chalk Talks : Basic and Translational Research**

What: Obtain feedback from the group on concepts and specific aims for grant proposals

When: 2nd Tuesday of every month from 9:00-10:00am

Where: Thurston Library (or hybrid)

Sign-up: contact Abby or Doug Phanstiel
Walk to Cure Arthritis 2024
Join the TARC Heels for the Walk to Cure Arthritis!

The Walk to Cure Arthritis is a nationwide event lead by the Arthritis Foundation. Please consider joining our team, the TARC Heels, as we walk to put an end to arthritis.

**What:** The Walk to Cure Arthritis  
**Where:** 201 Fenton Gtwy Dr, Cary, NC  
**When:** Saturday, June 8th at 9 am

Pets are welcome!
Questions?
Thank you for joining us!

Please take the remaining time to socialize and enjoy the provided refreshments.